Stakeholder Engagement Workshop on the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

National Institutes of Health Building 10, Lipsett Auditorium July 22, 2015

9:00 am – 9:15 am Welcome and Introduction

Carrie D. Wolinetz, Ph.D.

Associate Director for Science Policy, National Institutes of Health

9:15 am – 9:45 am Overview of the USG Policy for Institutional Oversight of Life Science Dual Use

Research of Concern

Susan Coller-Monarez, Ph.D.

White House Office of Science and Technology Policy

A review of the Dual Use Research of Concern (DURC) issue and details on the U.S. government policy for institutional oversight of DURC will be presented.

9:45 am - 11:00 am Case Study

<u>Moderator</u>: Lt. Marcienne Wright, Ph.D.

Office of Planning and Policy, ASPR, HHS

A hypothetical case study will be presented to illustrate the considerations that must be taken into account as investigators and Institutional Review Entities (IREs) consider whether research is subject to the USG policy for institutional oversight of DURC, and whether particular experiments or lines of research may constitute DURC.

11:00 am – 11:15 am **BREAK**

11:15 am – 12:00 pm Institutional Approaches: Processes for Identifying and Reviewing Research Subject to the Policy

A panel of institutional officials will share their experience setting up institutional systems for DURC oversight. The panelists will discuss how research subject to the policy is identified, the mechanisms used for registering the research with the IRE, and the administrative aspects of the review process; A discussion with the audience will follow.

Moderator: Samuel S. Edwin, Ph.D.

Chief, Biosecurity Division, USAMRIID

Panelists:

Trevor Ames, D.V.M.

Dean of the College of Veterinary Medicine, University of Minnesota

Robert Ellis, Ph.D., CBSP, SM (ASM), ACVM

University Director of Biosafety, Colorado State University

Philip Potter, Ph.D.

DURC Sub-Committee Chairman, St. Jude Children's Research Hospital

12:00 pm - 1:00 pm

Lunch (food to purchase in NIH cafeteria)

1:00 pm – 1:45 pm

Institutional Approaches: Developing Risk Mitigation Plans

A panel of institutional officials will discuss the steps in the development of risk mitigation plans for research determined to be DURC. A discussion with the audience will follow.

Moderators: Dennis Dixon, Ph.D.

Chief, Bacteriology and Mycology Branch, NIAID, NIH

Joe Kozlovac, M.S., RBP, CBSP Biological Safety Officer, ARS-USDA

Panelists:

Joseph Kanabrocki, Ph.D., CBSP

Associate Vice President for Research Safety, University of Chicago

Rebecca Moritz, M.S.

Select Agent Program Manager, University of Wisconsin

Philip Hauck, M.S., M.S.H.S., CIH, CBSP, SM (NRCM)
Institutional Biosafety Officer and Institutional Official

Icahn School of Medicine at Mt. Sinai

1:45 pm - 2:30 pm

Overview of USG Outreach Activities and Available Educational and Training Materials Related to the USG Policy for Institutional Oversight in Life Sciences Dual Use Research of Concern

Ryan Bayha

Senior Analyst for Biosecurity and Biosafety Policy, NIH

Information will be presented on the array of DURC outreach and education resources that have been developed by the US Government for institutions and investigators.

2:30 pm – 2:45 pm

BREAK

2:45 pm - 3:30 pm

Institutional Approaches: Raising Awareness and Educating about DURC

A panel of institutional representatives will present on their institution's approaches to educating on the requirements of the policy. A discussion with the audience will follow.

Moderator: Cheryl Doerr

Compliance Assurance Program Manager Department of Homeland Security

Panelists:

Stephen Higgs, Ph.D.
Associate Vice President for Research
Director, Biosecurity Research Institute, Kansas State University

Richard Frothingham, M.D., CBSP
Director, NIAID Regional Biocontainment Laboratory at Duke Medicine

Patricia Olinger, RBP
Assistant Vice President, Office of Research Administration
Executive Director, Environmental Health and Safety Office

Emory University

3:30 pm – 4:30 pm **Open Forum for Stakeholder Input/Future Directions**

Moderators: Representatives from various USG Departments and Agencies

An opportunity for participants to provide their input on issues relating to interpretation and implementation of the policy. The input provided will be used by the USG to tailor additional educational materials as needed.

A discussion of what additional resources may be helpful for institutions in order to assist in implementing the DURC policy effectively.

4:30 pm – 4:45 pm **Closing remarks**

Susan Coller-Monarez, Ph.D.

White House Office of Science and Technology Policy

4:45 pm Adjourn